Roundtable with Manufacturing Action Council/Regulatory Improvement Council/TALC
Remarks for Assistant Administrator Dunn
December 17, 2020

SLIDE 1: Presentation Title Slide

- Hello, I'm Alex Dunn, the Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention. Thank you for inviting me to speak to you today to highlight some of our work in EPA's chemical and pesticide management programs.

- I want to express my appreciation to the Manufacturing Action Council, the Regulatory Improvement Council and the Trade Association Leadership Council for having me here today.

- It's important that we take these opportunities to come together, share information, and listen to and learn from each other.

- It is especially a pleasure to be here in a year that marks the 50th Anniversary of EPA.

- As you may know, my office oversees the national implementation of several programs, including the Toxic Substances Control Act, or TSCA, the Federal Insecticide, Fungicide, and Rodenticide Act – or FIFRA – and the Pollution Prevention Act.

- I am incredibly proud of the way our work protects human health and the environment – now and for the future.

SLIDE 2: Guiding Principles

- All the work we've done, and will continue to do, is grounded in some of the goals we all share.

- Every day when I come to work, I am thinking of four things:
    - Protecting public health and the environment;
    - Improving engagement with stakeholders;
    - Increasing transparency and certainty in the work that we do; and

- Reducing unnecessary burden in our work.

- I'd like to highlight some of our accomplishments in both toxics and pesticides over the last year under these principles.

SLIDE 3: Protecting Public Health and the Environment

- First is the mission of EPA – to protect public health and the environment. Everything my office does every day supports this overarching goal.

- Over the last fiscal year, both the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics have reached impressive accomplishments in carrying out our mandate to protect you, your family, and the environment from potential risks from pesticides and toxic chemicals.

- I'd like to walk you through a few of our major accomplishments over the past few years so you can get a sense of the impact of our work.

- In our work to register safer pesticides and re-evaluate existing pesticides, we take action as necessary to protect public health and the environment. In addition, we have set up processes, policies, and resources to review over 40,000 existing chemicals in the marketplace as well as any new chemicals that companies want to bring to market.

- We've done this under incredibly tight timeframes and while still taking the time to ensure we're increasing transparency, producing high-quality work using sound science, and ensuring Americans are protected from unreasonable risks.

SLIDE 4: Protecting Public Health: First 10

- Starting with the Toxics side, we have and continue to make great progress on our risk evaluations.

- We are now working hard to finish finalizing the risk evaluations for the first ten chemicals.

- Because these documents will guide our future risk management actions, the agency is taking the time necessary to ensure they are high quality, reflect the best available science, and meet the necessary requirements under TSCA.

SLIDE 5: Protecting Human Health: Next 20 Chemicals

- While the focus of our TSCA work has been on the first 10 chemicals, at the same time we have been working hard on the next 20 chemicals to undergo risk evaluation as well.

- We issued the final scopes for these risk evaluations and are now developing draft risk evaluations for public comment.

- As we move through the risk evaluation process for these chemicals, we'll be working on identifying data gaps and gathering additional information as needed so we can ensure our evaluations are robust and use the best available science.

SLIDE 6: Protecting Human Health: PBT Chemicals

- I'd like to highlight one important priority on the horizon for this year which is to issue restrictions on five persistent, bioaccumulative and toxic chemicals.

- Last year we issued a proposed rule to reduce exposures to these chemicals and expect to issue final rules later this year.

- These chemicals build up in the environment over time. Addressing them is a critical way to focus on protecting the health of Americans – particularly vulnerable populations.

- As some of you may know, during this process of selecting PBT chemicals for expedited action under TSCA, we identified **two other PBT chemicals**. Last week we announced the receipt of a complete manufacturer-requested risk evaluation for these chemicals and two other chemicals in the same category. Within the next couple of months, we'll open up a public comment period on this request before making a decision to grant or deny the request.

- We worked diligently with manufacturers to ensure this request is high-quality, complete, and meets all the necessary legal requirements. Taking the time needed to work through the process required by TSCA will ultimately result in a robust risk evaluation that uses the best available science.

- These and all our successes implementing amended TSCA the past four years are a product of the amazing work our staff does every day, and I'd like to take a moment to thank them for that.

SLIDE 7: Protecting Public Health and the Environment: new active ingredients

New Active Ingredients

- One example of an important part of our work protecting public health in the pesticides space is registering new active ingredients and uses to address pest management challenges, providing lower-risk alternatives.

- In FY20, we registered 16 active ingredients, including:
    - Nootkatone, a biopesticide responsible for the smell and taste of grapefruit, which was discovered and developed by the Centers for Disease Control and Prevention to repel and kill ticks, mosquitoes, and a wide variety of other biting pests.

    - Alphachloralose, a novel rodenticide used to control mice inside homes and buildings, and the first new rodenticide active ingredient registered in over 20 years. It acts by lowering the body temperature in mice. Mice then experience hypothermia, enter a chemical-induced sleep, and die within as little as a few hours.

    - Another novel active ingredient we registered is NSPW Nanosilver for use in textiles, including fabrics, sportswear, footwear, linens, and awnings as a materials preservative.

- We are proud at EPA to support these innovations, which have the potential to do so much good.

SLIDE 8: Protecting Public Health and the Environment: registration review actions

Registration Review Actions
Let's move on from registration to a discussion of the registration review process. I'd like to give you an update on several high-profile pesticides going through our registration review process:

SLIDE 9: Protecting Public Health and the Environment: registration review actions - Atrazine

Atrazine
- In September, EPA released the interim decisions for the triazines (atrazine, propazine and simazine). This decision protects human health and mitigates ecological risks while continuing to provide farmers with valuable tools to control weeds.

- These mitigation measures will go into effect once EPA and the states approve the new labels.

SLIDE 10: Protecting Public Health and the Environment: registration review actions - Chlorpyrifos

Chlorpyrifos
- Chlorpyrifos, another widely used pesticide, is also undergoing registration review.

- EPA recently announced the publication of the ecological and revised human health draft risk assessments for chlorpyrifos.

- This Proposed Interim Decision was released to the public on Dec. 4.

SLIDE 11: Protecting Public Health and the Environment: registration review actions - Glyphosate

Glyphosate
- In early February 2020, EPA issued the Glyphosate Interim Decision, which included mitigation and label changes. These changes do three things: First, they target pesticide sprays on intended pests. Second, they protect pollinators. And third, they reduce the problem of weeds becoming resistant to glyphosate.

- After a thorough review of the best available science, as required under FIFRA, EPA concluded that there are no risks of concern to human health when glyphosate is used in accordance with its current label and that glyphosate is unlikely to be a human carcinogen.

- EPA's scientific findings on human health risk are consistent with the conclusions of science reviews by many other countries and other federal agencies.

- Last month, EPA released its draft biological evaluations for glyphosate for public review and comment.

- Biological evaluations are the beginning of EPA's Endangered Species Act consultation review process for pesticides where the agency determines whether the pesticide "may affect" one or more individuals of a listed species and their designated critical habitats.

- EPA will accept public comments on the draft evaluation for 60 days following its release. After carefully considering public comments and any additional data received, the agency will finalize the biological evaluation.

SLIDE 12: Protecting Public Health and the Environment: registration review actions – Rodenticides and Pyrethroids

Rodenticides

- The draft risk assessments for the rodenticides were completed this fiscal year.

- The next steps in the registration review process include public comment on the risk assessments, followed by the Proposed Interim Decision in early 2021.

- The Interim Decisions for the rodenticides are scheduled for late 2021.

Pyrethroids

- Throughout 2020, EPA published numerous proposed interim decisions as well as some interim decisions for the pyrethroids. EPA plans to publish the remaining pyrethroid interim decisions in 2021.

SLIDE 13: Protecting Public Health and the Environment: registration review actions – Neonicotinoids

Neonicotinoids

- In February 2020, EPA published the Proposed Interim Decisions for the neonicotinoids acetamiprid, clothianidin, dinotefuran, imidacloprid, and thiamethoxam.

- EPA proposed new measures reduce potential ecological risks, particularly to pollinators.

- This included proposing language on residential labels noting that products for use on ornamental plants are intended for use by professional applicators.

- If this mitigation is included in the Interim Decision, we expect it will reduce the likelihood of misapplication, overapplication, or spraying when pollinators are around, and therefore reduce risk to pollinators.

- The agency is also working with industry on developing and implementing stewardship and best management practices.

- Approximately 190,000 comments were received on the proposed interim decisions, including approximately 300 substantive comments.

- After reviewing public input, the agency anticipates issuing Interim Decisions in 2021.

SLIDE 14: Guiding Principles: Improving Engagement with Stakeholders

- Next, I want to turn another guiding principle of our work and speak about the goal of improving engagement with stakeholders. Many of our staff in this administration, including Administrator Wheeler, came to the EPA aiming to improve how the Agency engages with stakeholders. Hopefully by now you have seen a change.

- After working in the private sector for 23 years, one of the most important goals for me in coming to this position at EPA was to improve engagement.

- We rely on our stakeholders to bring things to our attention that we may not have considered, and to provide us with information we may not already have.

- Stakeholder engagement in our regulatory processes helps to ensure our decisions are based on the best available data and reflect real-world needs.

SLIDE 15: Improving Engagement with Stakeholders

TSCA Risk Management

- Stakeholders can expect transparent, proactive, and meaningful education, outreach, and engagement throughout the TSCA risk management process.

- Addressing the unreasonable risks we've found in some chemicals is going to be a difficult process, and we know that we need input, expertise, and feedback from stakeholders now – early in the process – to help shape the path forward.

- There will be several opportunities for us to gain this input, including public comment periods, webinars and required consultations with state and local governments, tribes, environmental justice communities, and small businesses. For example, we recently held public webinars on the first five final risk evaluations to educate stakeholders and get initial feedback on the risk management process.

FIFRA Engagement

- On the FIFRA side, outside of inviting public comments at several points in the registration and registration review process, EPA also hosts the Pesticide Program Dialogue Committee (PPDC), a Federal Advisory Committee Act (FACA) committee that provides a forum several times each year for a diverse group of stakeholders to give feedback to the pesticide program on various pesticide regulatory, policy and program implementation issues.

- We also have the FIFRA Scientific Advisory Panel (SAP), which is composed of biologists, statisticians, toxicologists and other experts who provide independent scientific advice to the EPA on a wide range of health and safety issues related to pesticides.

- These meetings are all open to the public and announced on the web, on the FIFRA SAP web page, and in the Federal Register.

- For both TSCA and FIFRA engagement, the goal is to end up with a path forward that mitigates risks and meets the needs of everyone involved in a thoughtful way. One example of this is our work with stakeholders on pollinator health. [next slide]

SLIDE 16: Improving Engagement with Stakeholders: Pollinators

Pollinators

- In September, EPA and USDA co-hosted the Pollinator State of Science Workshop webinar.

- This workshop provided participants, representing a wide range of stakeholders, an opportunity to discuss USDA-funded research which helps identify ways to improve pollinator health through collaborative efforts across government, industry, growers, academia and various other stakeholders.

- Beginning in March 2020, EPA hosted a series of 5 public webinars that reached an audience of thousands, highlighting ongoing work to promote pollinator health and habitat.

SLIDE 17: Guiding Principles: Increasing Transparency and Certainty in the Work That We Do

- The third guiding principle of my office's work is to increase transparency and certainty in the work that we do.

- We are committed to increasing transparency in both toxics and pesticides, but our New Chemicals Program is really taking transparency to the next level.

- We have put policies and procedures in place, standardized the review process, developed metrics to measure progress, and automated manual processes.

SLIDE 18: Increasing Transparency and Certainty in the Work That We Do: New Chemicals

- As of the beginning of December, the Agency has completed over 3,000 new chemical submissions and reduced the number of chemicals under review for over 90 days to approximately 182.

- And we aren't stopping there.

- It is our goal to continue to improve processes, increase efficiency, and keep this trend going as we drive to a 90-day review in the New Chemicals Program.

- Another way we have demonstrated our commitment to transparency is by making additional information about new chemical notices available to the public on the agency's website.

- I'm proud to say that we have provided the public with more information on new chemical submissions today than ever before.

SLIDE 19: Increasing Transparency and Certainty in the Work That We Do: Endangered Species Act (ESA) – Revised Method

- On the Office of Pesticide Programs side, one effort that EPA has undertaken to improve certainty is working with our federal partners to improve the consultation process required under the Endangered Species Act (ESA) for pesticide registration and registration review.

- We have been working collaboratively with our federal partners through the Interagency Working Group, which was formalized in December 2018 when President Trump signed the 2018 Farm Bill into law.

- EPA also hosted an Environmental Modeling Public Meeting (EMPM) in October 2019 on "Incorporation of Pesticide Usage Data into Environmental Exposure and Ecological Risk Assessments."

- In March of this year, EPA developed and released the Revised Method for Conducting National Level Listed Species Biological Evaluations of Conventional Pesticides, referred to as the Revised Method.

SLIDE 20: Increasing Transparency and Certainty in the Work That We Do: Endangered Species Act (ESA) – Revised Method

- The Revised Method was used to conduct draft biological evaluations (BEs) for methomyl and carbaryl, which were also released in March with the Revised Method.

- In April, EPA hosted a public webinar to present the draft BEs for carbaryl and methomyl and to answer questions from the public. We did this with the goal of improving the overall quality of comments from stakeholders during the public comment period.

- After considering comments received, EPA plans to issue the final BEs in early 2021 with a response to public comments.

SLIDE 21: Guiding Principles: Reducing Unnecessary Burden in Our Work

- Finally, when I come to work, I'm thinking about reducing the burden in our work. How we can collaborate to overcome redundancies that arise and slow us down?

- I challenge my staff to look for opportunities to reduce the burden we place on the regulated community without limiting the integrity of our work or the protection of America's environment and public health.

SLIDE 22: Guiding Principles: Reducing Unnecessary Burden in Our Work: Advancing Alternatives to Animal Testing

- An important way for us to reduce burden as we outgrow antiquated regulations is to advance alternatives to animal testing.

- As you may know, last September, the Administrator set several ambitious goals for the Agency with respect to prioritizing efforts to reduce animal testing, including eliminating all mammalian study requests and funding by 2035.

- In line with these efforts, we have a strategic plan to reduce the use of chemical testing on vertebrate animals in the TSCA program. We've also

released a list of acceptable New Approach Methodologies or "NAMs" that we continue to make progress in implementing.

SLIDE 23: Guiding Principles: Reducing Unnecessary Burden in Our Work: Revising TSCA Fees

- I also want to mention a new rulemaking process to update the TSCA fees rule. We made this announcement in March 2020 and the goal is to resolve implementation issues raised by stakeholders.

- The proposed rule would look at potential exemptions to the fees EPA charges manufacturers when it initiates risk evaluations.

- By narrowing the broad scope of the current requirements, the agency could significantly reduce burden on businesses across the country, while also maintaining the ability to successfully implement the Lautenberg Act amendments to TSCA designed to protect human health and the environment.

- More recently, EPA released the final list of companies subject to fees for the next 20 TSCA risk evaluations and started sending out invoices.

Due to the public health emergency, we are allowing for incremental payments of fees, providing needed flexibility and relief to businesses. Approximately 1/3 of the fee will be due in January with the remainder being due next September.

SLIDE 24: Reducing Unnecessary Burden in Responding to Public Health Emergencies: COVID-19

Pandemic/COVID flexibilities to approve products and new innovative products

- Of course, like everyone, EPA has been impacted by the COVID-19 public health emergency.

- OCSPP has been leading the charge to review and approve products that kill SARS-CoV-2, the virus that causes COVID-19, on surfaces.

- In this case, expediency has been paramount. That's why EPA triggered use of the Emerging Viral Pathogens guidance in January, allowing a pathway for

companies to make off-label claims for SARS-CoV-2 if they have data showing their products are effective against harder-to-kill viruses.

- Over the past several months we have expedited processes for reviewing new products and amendments to existing product labels.

- This work led to the creation of List N, which now includes over 500 products approved for use against SARS-CoV-2. The List can be accessed both on the web and by using a downloadable app. The website has been viewed more than 20 million times!

- We also developed a pathway for companies to add directions to product labels for application of disinfectants using electrostatic sprayers. Electrostatic spraying is especially important because of the need to disinfect large indoor spaces or areas with many surfaces.

SLIDE 25: Reducing Unnecessary Burden in Our Work: COVID-19

- To address supply chain issues in the pandemic, for certain active and inert ingredients, companies can now switch suppliers without waiting for EPA approval.

- EPA also created flexibilities for manufacturers by temporarily allowing companies to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval.

- In August, EPA used its authority under FIFRA Section 18 to issue an emergency exemption to the state of Texas to allow American Airlines and Total Orthopedics Sports & Spine to use SurfaceWise2, a surface coating that inactivates viruses and bacteria within two hours of application and continues to work against them for up to seven days.

- FIFRA Section 18 is more often used to address pest emergencies in agriculture, but the agency determined that by using it in this instance we could help to address the current national emergency and increase certainty and consumer confidence in resuming normal air travel and other activities.

- In October, EPA also released guidance for companies seeking to register products with "long-lasting" or "residual" efficacy against viruses like SARS-CoV-2. This guidance provides expedited path for our nation's manufacturers and innovators to get cutting-edge, long-lasting disinfecting products into the marketplace as safely and quickly as possible.

SLIDE 26: Reducing Unnecessary Burden in Our Work: COVID-19

- EPA is also aware that COVID-19 may make it difficult for employers to provide pesticide safety training or hire workers who have been trained in the last 12 months, as required by the Worker Protection Standard.

- In response, we issued guidance to inform employers of flexibilities available under the Worker Protection Standard to allow continued protection for employees and agricultural production.

- We've also issued temporary guidance that outlines approaches to address the unavailability of required respiratory protection and respiratory fit testing for agricultural pesticide handlers.

- In addition, we are aware that state, tribal, and federal certifying authorities may need to make temporary changes to their existing pesticide applicator certification programs in response to the COVID-19 public health emergency. As a result, we issued temporary guidance to provide flexibilities that meet both the needs of applicators and the requirements of the Certification of Pesticide Applicators rule.

- All these actions have enabled the regulated community to quickly respond to the needs created by the COVID-19 public health emergency.

- These flexibilities ensure EPA and stakeholders continue to work together to find ways to meet our shared goal of protecting public health during these unprecedented times.

SLIDE 27: Thank You!

- The message I want to leave you with is an assurance that EPA is working hard every day to find new and better ways to protect human health and the

environment, to improve transparency and engagement with stakeholders, to increase certainty, and to reduce unnecessary burden in our work.

- Thank you for allowing me to address this important audience today.